4. PROGRAM REGULATIONS

4. PROGRAM REGULATIONS (cont.)

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OUTPATIENT HOSPITAL MANUAL	TRANSMITTAL LETTER OPD-50	DATE 04/01/03

410.401: Introduction

130 CMR 410.000 establishes the requirements for the provision of services by hospital outpatient departments and hospital-licensed health centers under MassHealth. For the purposes of 130 CMR 410.000, "hospital outpatient department" refers to both hospital outpatient departments and hospital-licensed health centers. The Division pays for outpatient visits and ancillary services (such as radiographic views, laboratory tests, medical supplies, and pharmacy items) that are medically necessary and appropriately provided, as defined at 130 CMR 450.204. The quality of such services must meet professionally recognized standards of care. See 130 CMR 450.140 et seq. for regulations concerning Early and Periodic Screening, Diagnosis and Treatment (EPSDT).

410.402: Definitions

The following terms used in 130 CMR 410.000 have the meanings given in 130 CMR 410.402 unless the context clearly requires a different meaning. The reimbursability of services defined in 130 CMR 410.402 is not determined by these definitions, but by application of regulations elsewhere in 130 CMR 410.000, and in 130 CMR 415.000 and 450.000.

Acute Inpatient Hospital – a facility that is licensed as a hospital by the Massachusetts Department of Public Health and that provides diagnosis and treatment for patients who have any of a variety of medical conditions requiring daily physician intervention as well as full-time availability of physician services; however, this does not include any facility that is licensed as a chronic disease and rehabilitation hospital, any hospital that is licensed primarily to provide mental health services, or any unit of a facility that is licensed as a nursing facility, a chronic disease unit, or a rehabilitation unit.

Controlled Substance – a drug listed in Schedules II, III, IV, V, or VI of the Massachusetts Controlled Substances Act (M.G.L. c. 94C).

Cosmetic Surgery – a surgical procedure that is performed for the exclusive purpose of altering appearance and is unrelated to physical disease or defect, or traumatic injury.

Drug – a substance containing one or more active ingredients in a specified dosage form and strength. Each dosage form and strength is a separate drug.

Emergency – the unexpected onset of symptoms or a condition requiring immediate medical or surgical care, including, but not limited to, accidents and illnesses such as heart attack, stroke, poisoning, convulsions, loss of consciousness, and cessation of breathing.

Family Planning – any medically approved means, including diagnosis, treatment, and related counseling, that assists individuals of childbearing age, including sexually active minors, in determining the number and spacing of their children.

Functional Level – the degree to which an individual can function in the community. Progressive levels of impaired functioning are evaluated using a Division-approved scale that has specific criteria for emotional stability, vocational/educational productivity, social relations, and self-care.

Functional Maintenance Program – a planned combination of social, vocational, and recreational services designed for individuals disabled by a chronic mental illness who need continuing services to maintain skills that allow them to function within the community but who do not require the more intensive care of inpatient or day treatment programs.

Hospital – a facility that is licensed or operated as a hospital by the Massachusetts Department of Public Health or the Massachusetts Department of Mental Health and that provides diagnosis and treatment on an outpatient basis for patients who have any of a variety of medical conditions.

Hospital-Licensed Health Center – a facility not physically attached to a hospital that operates under the hospital's license, falls under the fiscal, administrative, and clinical management of the hospital, and provides services to patients on an outpatient basis.

Hospital Outpatient Department – a department or unit within the physical framework of the hospital that operates under the hospital's license and provides services to members on an outpatient basis. Hospital outpatient departments include day-surgery units, primary-care clinics, specialty clinics, and emergency departments.

Inpatient Services – medical services provided to a member admitted to an acute inpatient hospital.

Institutionalized Individual – an individual who is either:

(1) involuntarily confined or detained under a civil or criminal statute in a correctional or rehabilitative facility, including a psychiatric hospital or other facility for the treatment of mental illness; or

(2) confined under a voluntary commitment in a psychiatric hospital or other facility for the care and treatment of mental illness.

Interchangeable Drug Product – a product containing a drug in the same amounts of the same active ingredients in the same dosage form as another product with the same generic or chemical name that has been determined to be therapeutically equivalent (that is, "A-rated") by the Food and Drug Administration for Drug Evaluation and Research (FDA CDER), or by the Massachusetts Drug Formulary Commission.

Legend Drug – any drug for which a prescription is required by applicable federal or state law or regulation.

Maintenance Program — repetitive activities intended to maintain function that can be performed safely and effectively without the skilled assistance of a qualified therapist.

MassHealth Drug List – a list of commonly prescribed drugs and therapeutic class tables published by MassHealth. The MassHealth Drug List specifies the drugs that are payable under MassHealth. The list also specifies which drugs require prior authorization. Except for drugs and drug therapies described in 130 CMR 410.463(B), any drug that does not appear on the MassHealth Drug List requires prior authorization, as otherwise set forth in 130 CMR 410.000.

Mental Illness – mental and emotional disorders as defined in the current *International Classification of Diseases, Clinical Modification* or the American Psychiatric Association's *Diagnostic and Statistical Manual* and manifested by impaired functioning in one or more of the following: emotional stability, vocational/educational productivity, social relations, and self-care.

Mentally Incompetent Individual – an individual who has been declared mentally incompetent for any purpose by a federal, state, or local court of jurisdiction, unless the individual has been declared competent to consent to sterilization.

Multiple-Source Drug – a drug marketed or sold by two or more manufacturers or labelers, or a drug marketed or sold by the same manufacturer or labeler under two or more different names.

Nonlegend Drug – any drug for which no prescription is required by federal or state law.

Observation Services – outpatient hospital services provided anywhere in an acute inpatient hospital, to evaluate a member's condition and determine the need for admission to an acute inpatient hospital. Observation services are provided under order of a physician, consist of the use of a bed and intermittent monitoring by professional licensed clinical staff, and may be provided for more than 24 hours.

Occupational Therapy – evaluation and treatment that includes the administration and interpretation of tests necessary for effective treatment planning; the development of daily living skills, perceptual motor skills, sensory integrative functioning, play skills, and prevocational and vocational work capacities; the design, fabrication, or application of selected orthotic and prosthetic devices or selected adaptive equipment; the use of designated modalities, superficial heat and cold, and neuromuscular facilitation techniques to improve or enhance joint motion muscle function; the design and application of specific therapeutic activities and exercises to enhance or monitor functional or motor performance and to reduce stress; and the adaptation of environments for the handicapped.

Outpatient Hospital Services – medical services provided to a member in a hospital outpatient department. Such services include, but are not limited to, emergency services, primary-care services, observation services, ancillary services, day-surgery services, and recovery-room services.

Outpatient Services – medical services provided to a member in an outpatient setting including but not limited to hospital outpatient departments, hospital-licensed health centers, physicians' offices, nurse practitioners' offices, freestanding ambulatory surgery centers, day treatment centers, or the member's home.

Outpatient Visit – an in-person encounter between an eligible member and a licensed practitioner (such as a physician, optician, optometrist, or dentist) or other medical professional under the direction of a licensed practitioner for the provision of outpatient services as defined in 130 CMR 410.402.

Pharmacy On-Line Processing System (POPS) – the on-line, real-time computer network that adjudicates pharmacy claims, incorporating prospective drug utilization review, prior authorization, and member eligibility verification.

Physical Therapy – evaluation and treatment that includes the performance and interpretation of tests; the use of therapeutic exercise, physical activities, mobilization, functional and endurance training, traction, bronchopulmonary hygiene postural drainage, temporary splinting and bracing, massage, heat, cold, water, radiant energy, electricity, or sound; and instruction of both the patient and the family in physical-therapy procedures as part of a patient's ongoing program.

Reconstructive Surgery – a surgical procedure that is performed to correct, repair, or ameliorate the physical effects of physical disease or defect (for example, correction of a cleft palate), or traumatic injury.

Sheltered Workshop – a program of vocational counseling and training in which the participants receive paid work experience or other supervised employment.

Speech/Language Therapy – evaluation of speech, language, voice, and fluency disorders. Such treatment includes improvement of receptive and expressive language abilities, articulation, oral motor function, rate, rhythm, and vocal quality.

Sterilization – any medical procedure, treatment, or operation performed to make an individual permanently incapable of reproducing.

Trimester – one of three three-month terms in a normal pregnancy. If the pregnancy has existed for less than 12 weeks, the pregnancy is in its first trimester. If the pregnancy has existed for 12 or more weeks but less than 24 weeks, the pregnancy is in its second trimester. If the pregnancy has existed for 24 or more weeks, the pregnancy is in its third trimester. For the purposes of 130 CMR 410.000, the elapsed period of gestation is calculated in accordance with regulations of the Massachusetts Department of Public Health currently or hereafter in force.

Unit-Dose Distribution System — a means of packaging or distributing drugs, or both, devised by the manufacturer, packager, wholesaler, or retail pharmacist. A unit dose contains an exact dosage of medication and may also indicate the total daily dosage or the times when the medication should be taken.

Vocational Rehabilitative Services — services such as vocational assessments, job training, career counseling, and job placement.

410.403: Eligible Members

(A) (1) MassHealth Members. The Division covers outpatient hospital services only when provided to eligible MassHealth members, subject to the restrictions and limitations described in the Division's regulations. The Division's regulations at 130 CMR 450.105 specifically state, for each MassHealth coverage type, which services are covered and which members are eligible to receive those services.
(2) Recipients of the Emergency Aid to the Elderly, Disabled and Children Program. For information on covered services for recipients of the Emergency Aid to the Elderly, Disabled and Children Program, see 130 CMR 450.106.

(B) For information on verifying member eligibility and coverage type, see 130 CMR 450.107.

410.404: Provider Eligibility

Payment for the services described in 130 CMR 410.000 is made only to hospital outpatient departments participating in MassHealth on the date of service.

(A) In State
(1) To participate in MassHealth, acute hospital outpatient departments and hospital-licensed health centers located in Massachusetts must:
(a) operate under a hospital license issued by the Massachusetts Department of Public Health;
(b) have a signed provider agreement that specifies a payment methodology with the Division; and
(c) participate in the Medicare program.
(2) To participate in MassHealth, nonacute hospital outpatient departments located in Massachusetts must:
(a) operate under a hospital license issued by the Massachusetts Department of Public Health or the Massachusetts Department of Mental Health;
(b) have a rate or rates of payment established by the Massachusetts Division of Health Care Finance and Policy; and
(c) participate in the Medicare program.

(B) Out of State

(1) Out-of-state hospital outpatient and hospital-licensed health center services provided to an eligible MassHealth member are reimbursable in the following instances:

(a) emergency care hospital outpatient services are provided to a member;

(b) hospital outpatient services are provided to a member who lives in a community near the border of Connecticut, Maine, New Hampshire, New York, Rhode Island, or Vermont and for whom the out-of-state hospital is nearer than one in Massachusetts providing equivalent medical services;

(c) hospital outpatient services are provided to a member who is authorized to reside or who is placed out of state by the Massachusetts Department of Social Services or by a Chapter 766 core team evaluation;

(d) hospital outpatient services are provided to a member who has been authorized by the Division to reside in an out-of-state nursing facility; or

(e) prior authorization has been obtained from the Division for nonemergency services provided to a member by an out-of-state hospital outpatient department that is more than 50 miles from the Massachusetts border.

(2) To participate in MassHealth, an out-of-state hospital outpatient department or hospital-licensed health center must obtain a MassHealth provider number and meet the following criteria:

(a) it operates under a hospital license from or is approved as a hospital by the governing or licensing agency in its state;

(b) it participates in the Medicare program; and

(c) it participates in that state's medical assistance program (or the equivalent).

(3) Payment for out-of-state hospital outpatient and hospital-licensed health center services is made in accordance with the medical assistance program (or equivalent) fee schedule of that state.

410.405: Noncovered Services

(A) The Division does not pay for any of the following services:

(1) nonmedical services, such as social, educational, and vocational services;

(2) cosmetic surgery;

(3) maintenance therapy;

(4) canceled or missed appointments;

(5) telephone conversations and consultations;

(6) court testimony;

(7) research or the provision of experimental, unproven, or otherwise medically unnecessary procedures or treatments, specifically including, but not limited to, sex-reassignment surgery, thyroid cartilage reduction and any other related surgeries and treatments, including pre- and post-sex-reassignment surgery hormone therapy. Notwithstanding the preceding sentence, the Division will continue to pay for post-sex-reassignment surgery hormone therapy for which it had been paying immediately prior to May 15, 1993;

(8) the provision of whole blood; however, administrative and processing costs associated with the provision of blood and its derivatives are covered; and

(9) the treatment of male or female infertility (including, but not limited to, laboratory tests, drugs, and procedures associated with such treatment).

(B) The Division does not pay for mental health services such as, but not limited to, the following (see 130 CMR 410.472):

(1) vocational rehabilitation services;
(2) sheltered workshops;
(3) recreational services;
(4) life-enrichment services; and
(5) alcohol or drug drop-in centers.

(C) The Division does not pay for pharmacy services such as, but not limited to, the following (see 130 CMR 410.462 through 410.465):

(1) any drug used for the treatment of obesity;
(2) any drug used for smoking cessation;
(3) cough and cold preparations;
(4 less-than-effective drugs;
(5) hormone therapy related to sex-reassignment surgery; and
(6) drugs related to the treatment of male or female infertility.

(D) The Division does not pay for vision care services such as, but not limited to, the following (see 130 CMR 410.481 through 410.489):

(1) absorptive lenses of greater than 25 percent absorption;
(2) photochromatic lenses, sunglasses, or fashion tints;
(3) treatment of congenital dyslexia;
(4) extended-wear contact lenses;
(5) invisible bifocals; and
(6) the Welsh 4-Drop Lens.

(E) The Division does not pay an independent practitioner for services provided to members in an outpatient department except when that practitioner has an active provider number issued by the Division and meets one of the following criteria.

(1) The practitioner serves in an attending, visiting, or supervisory role at the hospital where the services are provided, is legally responsible for the management of the member's care, is physically present and actively involved in the treatment for which payment is claimed, and provides a service for which the Division pays an independent practitioner when provided in an outpatient hospital setting. Supervisory surgeons must be scrubbed and physically present during the major portion of an operation.
(2) The independent practitioner, if serving as a salaried intern, resident, fellow, or house officer, provides services during off-duty hours at an institution that does not pay his or her salary.
(3) The independent practitioner receives a salary from an institution for administrative or teaching services, but not for delivery of care, and provides direct medical care to a member that meets the conditions set forth in 130 CMR 410.405(E)(1).

410.406: Payment

(A) Acute hospital outpatient departments and hospital-licensed health centers in Massachusetts are paid for services provided to eligible members according to the rate for services established in the signed provider agreement with the Division, subject to the limitations set forth in 130 CMR 410.406.

(B) For purposes of making payments to acute hospital outpatient departments and hospital-licensed health centers in Massachusetts, the following limitations apply.

(1) The Division does not pay for outpatient services provided to a member who is an inpatient at the same or a different hospital on the same day.

(2) The Division pays only for emergency outpatient services provided to a member on the day that the member is discharged from the hospital, whether from the same or a different facility.

(3) If a member receives outpatient services at one facility and, later on the same day, is admitted as an inpatient to another facility, the Division pays both hospitals for services.

(4) When a member is admitted to inpatient status through the emergency department or outpatient department, the hospital must bill for only the inpatient stay. The Division does not pay for services furnished in the emergency department or outpatient department on the admitting day.

(C) Nonacute hospital outpatient departments in Massachusetts are paid for services provided to eligible members according to the MassHealth outpatient payment methodology established for each hospital by the Massachusetts Division of Health Care Finance and Policy (DHCFP), subject to the limitations set forth below.

(1) Charges.

(a) The Division pays only those charges contained in the charge book that the hospital has currently filed with DHCFP and no more than those charges.

(b) For changes in charges, the appropriate regulations of the DHCFP apply.

(c) In those cases where a specific rate has been established by DHCFP for a specific service or program (such as for adult day health services), the Division pays no more than that rate.

(2) Payments. For purposes of making payments to nonacute outpatient hospitals, the following limitations apply.

(a) The Division does not pay for outpatient services provided to a member who is an inpatient at the same or a different hospital on the same day.

(b) The Division pays only for emergency outpatient services provided to a member on the day that he or she is discharged from the hospital, whether from the same or a different facility.

(c) If a member receives outpatient services at one facility and, later on the same day, is admitted as an inpatient to another facility, the Division pays both hospitals for services.

(d) When a member is admitted to inpatient status through the emergency department or outpatient department, the hospital must bill for only the all-inclusive per diem rate for that day. The Division does not pay for services furnished in the emergency department or outpatient department on the admitting day.

(D) The Division pays for laboratory services in accordance with 130 CMR 410.456.

410.407: Certification

(A) Hospital outpatient departments must receive certification from the Division before providing the following services:

(1) adult day health services (for requirements, see 130 CMR 410.443);

(2) adult foster care services (for requirements, see 130 CMR 410.444); and

(3) psychiatric day treatment program services (for requirements, see 130 CMR 410.445).

(B) Hospital-based home health agencies must be certified by the Medicare program and must provide to MassHealth, upon its request, documentation of that certification.

410.408: Prior Authorization

(A) For certain outpatient services described in 130 CMR 410.000, MassHealth requires that the hospital outpatient department obtain prior authorization. No payment is made for outpatient services whenever a hospital is required, but fails, to obtain prior authorization from MassHealth or its designee. It is the responsibility of the hospital to obtain the necessary prior authorization.

(B) Prior authorization determines only the medical necessity of the authorized service and does not establish or waive any other prerequisites for payment, such as member eligibility or resort to health insurance payment.

(C) All requests for prior authorization must be submitted in accordance with the instructions in Subchapter 5 of the *Outpatient Hospital Manual*.

(D) Time requirements for response from MassHealth and rules that apply in determining the period within which MassHealth acts on specific requests for prior authorization are set forth in MassHealth's administrative and billing regulations in 130 CMR 450.000. A service is authorized on the date MassHealth transmits its decision about the request for prior authorization to the provider.

(E) Written notification of the prior-authorization decision is sent to the provider and indicates approval, deferral because additional information is necessary, modification, or denial. In the case of a modification or denial, the member is also notified. Notification of denial includes the reason for the decision. The member or the provider has the right to resubmit a request and provide additional information. The member may appeal the modification or denial of a prior-authorization request within 30 days after the date of the notice of denial. Procedures for such an appeal are set forth in 130 CMR 610.000.

(F) Members enrolled with a MassHealth managed care provider require service authorization before certain mental health and substance abuse services are provided. For more information, see 130 CMR 450.124.

(G) The hospital must obtain prior authorization for the following outpatient therapy services:
(1) more than eight occupational-therapy visits or eight physical-therapy visits, including a comprehensive evaluation and group-therapy visits, for a member within a 12-month period; and
(2) more than 15 speech/language therapy visits, including a comprehensive evaluation and group-therapy visits, for a member within a 12-month period.

410.409: Recordkeeping (Medical Records) Requirements

(A) Payment for any outpatient service covered by MassHealth is conditioned upon its full and complete documentation in the member's medical record. If the information in the member's record is not sufficient to document the service for which payment is claimed by the provider, MassHealth will not pay for the service or, if payment has been made, will consider such payment to be an overpayment subject to recovery as defined in MassHealth's administrative and billing regulations in 130 CMR 450.000. Medical record requirements as set forth in 130 CMR 410.000 constitute the standard against which the adequacy of records is measured, as set forth in 130 CMR 450.000.

(B) MassHealth may request, and the hospital outpatient department must provide, any and all medical records (or clear photocopies of such records) corresponding to or documenting the services claimed, in accordance with M.G.L. c. 118E, § 38, and 130 CMR 450.000. All components of a member's complete medical record (such as lab slips and X rays) do not need to be maintained in one file as long as all components are accessible to MassHealth upon its request.

(C) The medical record must contain sufficient data to document fully the nature, extent, quality, and necessity of the care provided to a member for each date of service claimed for payment, as well as any data that will update the member's medical course. The data maintained in the member's medical record must also be sufficient to justify any further diagnostic procedures, treatments, recommendations for return visits, and referrals.

(D) Although basic data collected during previous visits (such as identifying data, chief complaint, or history) need not be repeated in the member's medical record for subsequent visits, the medical records for hospital outpatient services provided to members must include at least the following information:

(1) the member's name and date of birth;
(2) the date of each service;
(3) the reason for the visit;
(4) the name and title of the person who performed the service;
(5) the member's medical history;
(6) the diagnosis or chief complaint;
(7) a clear indication of all findings, whether positive or negative, on examination;
(8) any tests administered and their results;
(9) a description of any treatment given;
(10) any medications administered or prescribed, including strength, dosage, regimen, and duration of use;
(11) any anesthetic agent administered;
(12) any medical goods or supplies dispensed or supplied;
(13) recommendations and referrals for additional treatments or consultations, when applicable;
(14) the federally required consent form for sterilization or hysterectomy, when applicable; and
(15) such other information as is applicable for the specific service provided, or as is otherwise required in 130 CMR 410.000.

(E) When a member is referred from a private physician to a hospital outpatient department exclusively for the purpose of a diagnostic test, the following information, at a minimum, must be included in the member's medical record:

(1) the member's name and date of birth;
(2) the signed referral from the private physician authorizing the procedure;
(3) the date of service;
(4) the name and title of the person who performed the service; and
(5) a clear indication of all findings, whether positive or negative.

(F) For therapist services, in addition to the applicable information required in 130 CMR 410.409(D), the member's medical record must include at least the following (see 130 CMR 410.453);

(1) a licensed physician's written referral for evaluation, referral for treatment, and renewal of referral (if applicable) every 60 days (see 130 CMR 410.451(B));
(2) the written comprehensive evaluation report (see 130 CMR 410.451(C));
(3) the name, address, and telephone number of the member's primary physician;
(4) a treatment notation for each date on which therapy was provided that includes at least the following:
  (a) the specific therapeutic procedures and methods used;
  (b) the amount of time spent in treatment; and
  (c) the signature and title of the person who provided the service;
(5) at least weekly documentation of the following:
  (a) the member's response to treatment;
  (b) any changes in the member's condition;
  (c) the problems encountered or changes in the treatment plan or goals, if any;
  (d) the location where the service was provided if different from that in the evaluation report; and
  (e) the signature and title of the therapist; and
(6) a discharge summary, when applicable.

(G) (1) For mental health services, in addition to the applicable information required in 130 CMR 410.409(D), the member's medical record must include at least the following (see 130 CMR 410.478):

(a) the member's case number, address, telephone number, sex, age, marital status, next of kin, and school or employment status (or both);
(b) the date of initial contact and, if applicable, the referral source;
(c) a report of a physical examination performed within six months (if such an examination has not been performed in that period, one must be given within 30 days after the member's request for services or, if the member refuses to be examined, the record must document the reasons for the exam postponement);
(d) the name and address of the member's primary physician or medical clinic (a physician or medical clinic must be recommended if there is not one currently attending the member);
(e) a description of the nature of the member's condition;
(f) the relevant medical, social, educational, and vocational history;
(g) a comprehensive functional assessment of the member;
(h) the clinical impression of the member and a diagnostic formulation, including a specific diagnosis using ICD-9-CM or DSM III diagnosis codes;
(i) the member's treatment plan, updated as necessary, including long-range goals, short-term objectives, and the proposed schedule of therapeutic activities;

(j) a schedule of dates for utilization review to determine the member's progress in accomplishing goals and objectives;
(k) the name, qualifications, and discipline of the primary therapist;
(l) a written record of utilization reviews by the primary therapist;
(m) documentation of each visit, including the member's response to treatment, written and signed by the person providing the service, and including the therapist's discipline and degree;
(n) all information and correspondence about the member, including appropriately signed and dated consent forms;
(o) a medication-use profile; and
(p) when the member is discharged, a discharge summary.

(2) A brief history is acceptable for emergency or walk-in visits when the treatment plan does not call for extended care.

(H) Hospital pharmacies must maintain a record for each member of the drug and amount dispensed, the date, and the original prescription (see 130 CMR 410.467).

(I) For vision care services, in addition to the applicable information required in 130 CMR 410.409(D), the record must fully disclose all pertinent information about the services provided, including the date of service, the dates on which materials were ordered and dispensed, and a description of materials (including the frame style and the manufacturer's name) ordered and dispensed (see 130 CMR 410.483).

(1) All health care findings resulting from a visual analysis, whether they are normal or abnormal, must be recorded. When extenuating circumstances prevent the use of one or more procedures normally done in a visual analysis, the record must contain the reasons that the tests were not performed.

(2) For comprehensive eye examinations and diagnoses, the record must contain the following information or test results:
(a) case history;
(b) visual acuity testing;
(c) ophthalmoscopy and external eye health examination;
(d) ocular mobility testing, heterophoria testing, and fusion testing;
(e) pupillary reflex testing;
(f) refraction (retinoscopy, subjective refraction, and keratometry);
(g) confrontation fields or other screening tests;
(h) tonometry, when medically indicated;
(i) case analysis and disposition; and
(j) biomicroscopy, when medically indicated.

(3) All consultation services must be fully documented in the record. A record for a consultation must contain the following information:
(a) the member's complaints and symptoms;
(b) the condition of the eye; and
(c) if applicable, the name of the person to whom a referral was made.

(4) All screening services must be fully documented in the record. A record for a screening service must note the chief complaint and must contain all findings of two or more of the following tests:

(a) visual acuity;
(b) distance vision and near vision;
(c) cover test;
(d) visual skills;
(e) tonometry; and
(f) biomicroscopy.

(J) For laboratory services, in addition to the applicable information required in 130 CMR 410.409(D) above, the recipient's medical record must contain a suitable record of each specimen and laboratory test result for at least six years from the date on which the results were reported to the prescriber (see 130 CMR 410.458):

(1) the name and any other means of identification of the person from whom the specimen was taken;
(2) the name of the prescriber or laboratory that submitted the specimen;
(3) the authorized requisition or order, or both;
(4) the location where the specimen was taken, if other than the hospital outpatient department;
(5) the date on which the specimen was collected by the prescriber or laboratory;
(6) the date on which the specimen was received in the laboratory;
(7) the condition of unsatisfactory specimens when received (for example, broken, leaked, hemolyzed, turbid, or insufficient sample size);
(8) the date on which the test was performed;
(9) the test name and the results of the test, or the cross-reference to results and the date of reporting; and
(10) the name and address of the laboratory to which the specimen was referred, if applicable.

410.410: Assurance of Recipient Rights

No provider shall use any form of coercion in the provision of any services (for example, abortion, sterilization, and family planning). Neither the Division nor any provider, nor any agent or employee of a provider, shall mislead any recipient into believing that a decision to receive any services reimbursable under these regulations will adversely affect the recipient's entitlement to benefits or services for which the recipient would otherwise be eligible. The Division has strict requirements for the confidentiality of patient records for all medical services reimbursable under the Medical Assistance Program.

410.411: Emergency Services

(A) The Division will pay for emergency services provided in a hospital emergency room only when such services are medically necessary and the necessity is fully documented in the recipient's medical record.

(B) For services provided in the emergency department, handwritten or time-stamped documentation of the length of the recipient's stay in the emergency room must be kept in the recipient's record or on an easily accessible hospital log.

(C) For recipients participating in MassHealth Managed Care who are enrolled in the PCC Plan (see 130 CMR 450.101), the Division pays for urgent care and for emergency care in accordance with 130 CMR 450.118(I).

(D) The Division requires under certain conditions that recipients make a copayment to the hospital for nonemergency services provided in an emergency room. The copayment requirements are detailed in the Division's administrative and billing regulations at 130 CMR 450.130.

410.412: Utilization Management Program and Mental Health and Substance Abuse Admission Screening Requirements

(A) Utilization Management Program. The Division will pay for procedures and hospital stays that are subject to the Utilization Management Program only if the applicable requirements of the program as described in 130 CMR 450.207 through 450.211 are satisfied. Appendix H of the Outpatient Hospital Manual contains the name, address, and telephone number of the contact organization for the Utilization Management Program and describes the information that must be provided during the review process.

(B) Mental Health and Substance Abuse Admissions. The Division will pay for mental health and substance abuse services provided in an acute or nonacute inpatient setting only if the admitting provider has satisfied the screening requirements at 130 CMR 450.125. Appendix E of the Outpatient Hospital Manual contains the name, address, and telephone number of the contact organization for the screening program.

410.413: Medical Services Required on Site at a Hospital-Licensed Health Center

In order to be reimbursed at the rates established for hospital-licensed health centers (HLHCs), an HLHC must provide on site the medical services specified in 130 CMR 410.413(D), (E), and (F), and at least two of the medical services described in 130 CMR 410.413(A), (B), and (C). It is not necessary that all of these services be available during all hours of the HLHC's operation, but all services must be available to members on a regularly scheduled basis with sufficient frequency to ensure access to care and continuity of care.

(A) Pediatric Services. The HLHC must provide pediatric services.

(B) Internal Medicine. The HLHC must provide internal medicine services.

(C) Obstetrics/Gynecology. The HLHC must provide obstetrical and gynecological services. When a family practitioner is employed in place of a medical specialist in obstetrics/gynecology, the family practitioner must have admitting privileges to a hospital for delivery and obstetrical and gynecological backup.

(D) Health Education. The HLHC must provide health education designed to prepare members for their participation in and reaction to specific medical procedures, and to instruct members in self-management of medical problems and in disease prevention. Health education may be provided by any health practitioner or by any other individual approved by the HLHC's professional services director as possessing the qualifications and training necessary to provide health education to members.

(E) Medical Social Services. The HLHC must provide medical social services designed to assist members in their adjustment to and management of social problems resulting from medical treatment, specific disease episodes, or chronic illness. Medical social services must be provided by a clinical social worker who is licensed by the Massachusetts Board of Registration. This individual must be on site sufficient hours and with sufficient frequency to provide medical social services to members.

(F) Nutrition Services. The HLHC must provide counseling in the purchase, preparation, and consumption of proper nutrients to members who have been determined to require such counseling because of their health problems or because they have a high potential for developing health problems that might be avoided or made less severe through proper nutrition. Each HLHC must employ either a nutrition professional with a bachelor's or master's degree in public health nutrition, community nutrition, or human nutrition, or a dietitian who is currently registered by the American Dietetic Association. This individual is responsible for planning, directing, and evaluating the nutrition services provided at the HLHC; for educating the HLHC's staff about nutrition; for supervising any nutrition aides; for consulting with practitioners and other staff members of the HLHC; and for counseling members referred for nutrition information. The nutrition professional or registered dietitian must be on site at least one day per calendar month.

410.414: Observation Services

(A) Reimbursable Services. The Division covers medically necessary observation services provided by acute inpatient hospitals. Reimbursable observation services may exceed 24 hours, and do not need to be provided in a distinct observation unit. To qualify for reimbursement of observation services, the medical record must specifically document when those services began and ended, the purpose of observation, and the name of the physician who ordered it. Acute inpatient hospitals will be reimbursed for these observation services on an outpatient basis in accordance with the signed provider agreement with the Division.

(B) Nonreimbursable Services.

(1) Nonreimbursable observation services include but are not limited to:

(a) services that are not reasonable or necessary for the diagnosis or treatment of the member; and

(b) routine preparation and recovery services associated with diagnostic testing or outpatient surgery.

(2) The following services are not reimbursable as a separate service:

(a) postoperative monitoring during a standard recovery period that should be characterized as recovery-room services; and

(b) observation services provided concurrently with therapeutic services such as chemotherapy.

(130 CMR 410.415 through 410.430 Reserved)

410.431: Sterilization Services: Introduction

(A) Eligible Recipients. Medical Assistance recipients in categories of assistance 0, 1, 2, 3, 5, 6, 7, and 8 are eligible for sterilization services as described in 130 CMR 410.431 through 410.433. For information on reimbursable services for recipients of the Emergency Aid to the Elderly, Disabled and Children Program (category of assistance 4), see 130 CMR 450.111.

(B) Definitions. The following definitions apply to sterilization services:

(1) Sterilization — any medical procedure, treatment, or operation that renders an individual permanently incapable of reproducing. A sterilization is "nontherapeutic" when the individual has chosen sterilization as a permanent method of contraception. A sterilization is "therapeutic" when it occurs as a necessary part of the treatment of an existing illness or injury or is medically indicated and performed in conjunction with surgery upon the genito-urinary tract.

(2) Mentally Incompetent Individual — an individual who has been declared mentally incompetent by a federal, state, or local court of competent jurisdiction for any purpose, unless the individual has been declared competent for purposes that include the ability to consent to sterilization.

(3) Institutionalized Individual — an individual who is:

(a) involuntarily confined or detained, under a civil or criminal statute in a correctional or rehabilitative facility, including a psychiatric hospital or other facility for the care and treatment of mental illness; or

(b) confined, under a voluntary commitment, in a psychiatric hospital or other facility for the care and treatment of mental illness.

(C) Reimbursable Services. The Division will pay for a male or a female sterilization performed by a licensed physician in a hospital outpatient department only if all of the following conditions are met.

(1) The recipient has voluntarily given informed consent for the sterilization procedure in the manner and at the time described in 130 CMR 410.432, and such consent is documented in the manner described in 130 CMR 410.433.

(2) The recipient is at least 18 years old at the time consent is obtained.

(3) The recipient is not mentally incompetent or institutionalized.

(D) Assurance of Recipient Rights. No provider shall use any form of coercion in the provision of sterilization services. Neither the Division nor any provider, nor any agent or employee of a provider, shall mislead any recipient into believing that a decision to have or not to have a sterilization will adversely affect the recipient's entitlement to benefits or services for which the recipient would otherwise be eligible. The Division has strict requirements for confidentiality of recipient records for sterilization services as well as for all other medical services reimbursable under the Medical Assistance Program.

(E) Retroactive Eligibility. The Division will not pay for a sterilization performed during the period of a recipient's retroactive eligibility unless all conditions for payment listed in 130 CMR 410.431(C) are met.

410.432: Sterilization Services: Informed Consent

A recipient's consent for sterilization will be considered informed and voluntary only if such consent is obtained in accordance with the requirements specified in 130 CMR 410.432(A) and (B).

(A) Informed Consent Requirements.

(1) The person who obtains consent (a physician, nurse, or counselor, for example) must orally provide all of the following information and advice to the recipient requesting sterilization:

(a) advice that the recipient is free to withhold or withdraw consent for the procedure at any time before the sterilization without affecting the right to future care or treatment and without loss of any federal- or state-funded program benefits to which the recipient otherwise might be entitled;

(b) a description of available alternative methods of family planning and birth control;

(c) advice that the sterilization procedure is considered irreversible;

(d) a thorough explanation of the specific sterilization procedure to be performed;

(e) a full description of the discomforts and risks that may accompany or follow the procedure, including an explanation of the type and possible effects of any anesthetic to be used;

(f) a full description of the benefits or advantages that may be expected as a result of the sterilization; and

(g) advice that the sterilization will not be performed for at least 30 days, except under the circumstances specified in 130 CMR 410.432(B)(1).

(2) The person who obtains consent must also:
(a) offer to answer any questions the recipient may have concerning the sterilization procedure;
(b) give the recipient a copy of the consent form;
(c) make suitable arrangements to ensure that the information and advice required by 130 CMR 410.432(A)(1) are effectively communicated to any recipient who is blind, deaf, or otherwise handicapped;
(d) provide an interpreter if the recipient does not understand the language used on the consent form or the language used by the person obtaining consent; and
(e) allow the recipient to have a witness of the recipient's choice present when consent is obtained.

(B) When Informed Consent Must Be Obtained.
(1) A recipient's consent for sterilization will be considered informed and voluntary only if such consent is obtained at least 30 days, but not more than 180 days, before the date of the sterilization procedure, except in the case of premature delivery or emergency abdominal surgery. A recipient may not be sterilized at the time of a premature delivery or emergency abdominal surgery unless at least 72 hours have passed since the recipient gave informed consent for the sterilization in the manner specified in 130 CMR 410.432(A). In the case of premature delivery, the informed consent must have been given at least 30 days before the expected date of delivery.
(2) A recipient's consent for sterilization will not be considered informed or voluntary if such consent is obtained or given while the recipient requesting sterilization is:
(a) in labor or childbirth;
(b) seeking to obtain or obtaining an abortion; or
(c) under the influence of alcohol or other substances that affect the individual's state of awareness.
(3) Shortly before the performance of the sterilization procedure, the physician performing the procedure must orally inform the recipient of all of the information and advice specified in 130 CMR 410.432(A)(1).

410.433: Sterilization Services: Consent Form Requirements

Informed consent for sterilization must be documented by the completion of the Division's Consent for Sterilization form in accordance with the following requirements. (Instructions for obtaining the Consent for Sterilization forms are located in Subchapter 5 of the Outpatient Hospital Manual.)

(A) Required Consent Form.
(1) One of the following Consent for Sterilization forms must be used:
(a) CS-18 — for recipients aged 18 through 20; or
(b) CS-21 — for recipients aged 21 and older.
(2) Under no circumstances will the Division accept any other consent for sterilization form.

(B) Required Signatures. The recipient, the interpreter (if one was required), and the person who obtained the consent for sterilization must all sign and date the Consent for Sterilization form (CS-18 or CS-21) at the time of consent. After performing the sterilization procedure, the physician must sign and date the form.

(C) Required Submission and Distribution of the Consent Form. The Consent for Sterilization form (CS-18 or CS-21) must be completed and distributed as follows:
(1) the original must be given to the recipient at the time of consent;
(2) a copy must be included in the recipient's permanent medical record at the site where the sterilization is performed; and
(3) all providers must attach a copy of the completed Consent for Sterilization form (CS-18 or CS-21) to each claim made to the Division for sterilization services. When more than one provider is billing the Division (for example, the physician and the hospital), each provider must submit a copy of the completed consent form.

410.434: Abortion Services: Reimbursable Services

The Division will pay for first- and certain second-trimester abortions performed by a licensed physician in a hospital outpatient department only when all of the following conditions are met:

(A) the abortion is performed in accordance with M.G.L. c. 112, ss. 12K through 12U, except as provided under 130 CMR 484.005(B);

(B) the abortion is medically necessary—that is, according to the medical judgment of a licensed physician, necessary in light of all factors affecting the woman's health; and

(C) the abortion service is claimed according to the requirements in 130 CMR 410.435.

410.435: Abortion Services: Certification for Payable Abortion Form

All physicians and hospital outpatient departments must attach a completed Certification for Payable Abortion (CPA-2) form to each claim form submitted to the Division for a payable abortion. (Instructions for obtaining the Certification for Payable Abortion form are in Subchapter 5 of the Outpatient Hospital Manual.) To identify those abortions that meet federal reimbursement standards specified in 42 CFR, the Division must secure on the CPA-2 form the certifications described in 130 CMR 410.435(A), (B), and (C), when applicable. For all medically necessary abortions not included in 130 CMR 410.435(A), (B), or (C), the certification described in 130 CMR 410.435(D) is required on the CPA-2 form. The physician who performs the abortion must indicate on the CPA-2 form which of the following circumstances is applicable, and must complete that portion of the form with the appropriate signatures.

(A) Life of the Woman Would Be Endangered. The attending physician must certify that, in his or her professional judgment, the life of the woman would be endangered if the pregnancy were carried to term.

(B) Severe and Long-Lasting Damage to the Woman's Physical Health. The attending physician and another physician must each certify that, in his or her professional judgment, severe and long-lasting damage to the woman's physical health would result if the pregnancy were carried to term. At least one of the physicians must also certify that he or she is not an "interested physician," defined herein as one whose income is directly or indirectly affected by the fee paid for the performance of the abortion; or who is the spouse of, or another relative who lives with, a physician whose income is directly or indirectly affected by the fee paid for the performance of the abortion.

(C) Victim of Rape or Incest. The physician is responsible for submitting with the claim form signed documentation from a law enforcement agency or public health service certifying that the woman upon whom the procedure was performed was a victim of rape or incest that was reported to the agency or service within 60 days of the incident. (A public health service is defined as either an agency of the federal, state, or local government that provides health or medical services, or a rural health clinic, provided that the agency's principal function is not the performance of abortions.) The documentation must include the date of the incident, the date the report was made, the name and address of the victim and of the person who made the report (if different from the victim), and a statement that the report included the signature of the person who made the report.

(D) Other Medically Necessary Abortions. The attending physician must certify that, in his or her medical judgment, for reasons other than those described in 130 CMR 410.435(A), (B), and (C), the abortion performed was necessary in light of all factors affecting the woman's health.

410.436: Abortion Services: Out-of-State Abortions

The Division will pay for an abortion performed in an out-of-state facility only if the abortion meets the conditions specified in 106 CMR 410.434 and if prior authorization is requested and received from the Division.

(A) The recipient, the referring physician, the hospital outpatient department, or a referral agency may request prior authorization from the Division in writing. The request must be made in accordance with the instructions for requesting prior authorization for abortion services in Subchapter 5 of the Outpatient Hospital Manual.

(B) If the Division authorizes the abortion, it will issue a prior authorization slip directly to the out-of-state facility. The facility must attach the prior authorization slip to the claim form when requesting payment from the Division.

(C) Out-of-state abortion services will be authorized only when such services are not available in a Massachusetts facility.

(D) Prior authorization is not required for abortion services provided in the situations described in 106 CMR 410.404(B)(1).

410.437: Family Planning Services

(A) Reimbursable Services. The Division will pay for hospital outpatient services related to the timing and spacing of children. These services may include but are not limited to the following:

(1) nonpermanent contraceptive care;
(2) comprehensive medical examination;
(3) diagnosis and treatment of medical problems specific to reproduction as well as diagnosis of and appropriate referral for other medical problems;
(4) venereal disease testing and treatment;
(5) cervical cancer screening (Pap smear);
(6) breast examination;
(7) laboratory services related to family planning (for example, Pap smear, gonorrhea culture, vaginal culture and smear, blood test for venereal disease, hematocrit, complete blood count, urinalysis, and pregnancy testing); and
(8) family planning counseling, including discussions about family planning, human reproduction, and methods of contraception.

(B) The Norplant System of Contraception.

(1) Eligible Providers. The Division will pay outpatient departments for the insertion, reinsertion, and removal of the Norplant System of Contraception (Norplant) when the services are provided by a salaried physician, nurse practitioner, nurse midwife, or physician assistant. In order for the hospital to claim payment for Norplant services, the clinician performing the procedure must be trained by either the manufacturer of Norplant or another clinician who has been trained by the manufacturer.

(2) Patient Selection, Counseling Prior to Insertion, and Follow-Up.

(a) In order to prevent premature removal of Norplant, the Division requires careful patient selection and counseling prior to insertion. Counseling must be in accordance with the manufacturer's guidelines, and must include a detailed discussion of potential side effects, contraindications, benefits and risks, and other contraceptive options.

(b) A visit following insertion is also required as a condition of reimbursement. The visit must include an examination of the insertion site for complications, a review of potential side effects, and follow-up instructions. If more than one follow-up visit is necessary, the provider should bill each as a separate visit.

(c) The provider must make every effort possible to ensure that the recipient returns for the follow-up visit. This shall include, but not be limited to, scheduling the follow-up appointment on the day of insertion, recording the day of the follow-up appointment in the recipient's chart, mailing a reminder notice to the recipient, and reminding the recipient by telephone during the week of the scheduled appointment. The provider must document in the medical record the efforts made to ensure that the recipient returns for the follow-up visit. In order to ensure payment for the procedure, the provider must also document if the recipient fails to return for the follow-up visit.

(3) Service Limitations.

(a) The Division will pay for the insertion and reinsertion of Norplant for female recipients of childbearing age with menstrual histories. The Department will pay for the removal of Norplant for female recipients of all ages.

(b) The Division will pay for the insertion or reinsertion of Norplant only once per recipient per five-year period.

(c) If the recipient has a Norplant device implanted, no other form of contraception should be prescribed, with the exception of condoms. If the Norplant device is removed for any reason, however, the Division will pay for alternative types of contraception.

(106 CMR 410.438 through 410.440 Reserved)

410.441: Early Intervention Program Services

(A) An early intervention program provides services such as therapy and social, medical, educational, and developmental services for children aged three years or younger who are at biological, environmental, or established risk, and for their families.

(B) The Division pays for services provided as part of an organized early intervention program by hospital outpatient departments. These services must be furnished in compliance with the Division's regulations governing early intervention program services in 130 CMR 440.000. (See Subchapter 5 of the Outpatient Hospital Manual for instructions about obtaining the Early Intervention Program Manual, which contains the necessary regulations.)

(C) Acute hospital-based early intervention programs will be paid according to the outpatient reimbursement methodology established by the signed provider agreement with the Division.

(D) Nonacute hospital-based early intervention programs will be paid according to the outpatient reimbursement methodology established by the Massachusetts Rate Setting Commission (see 130 CMR 410.406).

410.442: Home Health Agency Services

(A) A home health agency is a public or private agency or organization, or a subdivision of such an agency or organization, that is primarily engaged in furnishing part-time skilled nursing and other therapeutic services to patients in their homes.

(B) The Division pays for home health services provided by hospital-based home health agencies. These services must be furnished in compliance with the Division's regulations governing home health agency services in 130 CMR 403.000. (See Subchapter 5 of the Outpatient Hospital Manual for information about obtaining the Home Health Agency Manual, which contains the necessary regulations.)

(C) Acute hospital-based home health agencies will be paid according to the outpatient reimbursement methodology established by the signed provider agreement with the Division.

(D) Nonacute hospital-based home health agencies will be paid according to the outpatient reimbursement methodology established by the Massachusetts Rate Setting Commission (see 130 CMR 410.406).

410.443: Adult Day Health Program Services

(A) An adult day health program is an organized program of health care and supervision, restorative services, and social activities whose general goal is to provide an alternative to long-term institutional care.

(B) The Division pays for services provided as part of an organized adult day health program by a hospital outpatient department. These services must be furnished in accordance with the Division's regulations governing adult day health programs in 130 CMR 404.000. (See Subchapter 5 of the Outpatient Hospital Manual for information about obtaining the Adult Day Health Manual, which contains the necessary regulations.)

(C) Acute hospital-based adult day health programs will be paid according to the outpatient reimbursement methodology established by the signed provider agreement with the Division.

(D) Nonacute hospital-based adult day health programs will be paid according to the outpatient reimbursement methodology established by the Massachusetts Rate Setting Commission (see 130 CMR 410.406).

410.444: Adult Foster Care Services

(A) An adult foster care program provides room, board, and personal care services in a family-like setting to elderly or disabled individuals who are at imminent risk of institutional placement.

(B) The Division pays for services provided by hospital-based adult foster care programs. These services must be furnished in compliance with the "Adult Foster Care Guidelines" issued by the Division. (See Subchapter 5 of the Outpatient Hospital Manual for information about obtaining the "Guidelines" and the Adult Foster Care Manual.)

(C) Acute hospital-based adult foster care programs will be paid according to the outpatient reimbursement methodology established by the signed provider agreement with the Division.

(D) Nonacute hospital-based adult foster care programs will be paid according to the reimbursement methodology established by the Office of Purchased Services in the Executive Office of Administration and Finance.

410.445: Psychiatric Day Treatment Program Services

(A) A psychiatric day treatment program is a planned combination of diagnostic, treatment, and rehabilitative services provided to mentally or emotionally disturbed persons who need more active or inclusive treatment than is typically available through a weekly visit for outpatient mental health services, but who do not need full-time hospitalization or institutionalization. Such a program uses multiple, intensive, and focused activities in a supportive environment to enable these individuals to acquire more realistic and appropriate behavior patterns, attitudes, and skills for eventual independent functioning in the community.

(B) MassHealth pays for services provided as part of an organized psychiatric day treatment program by hospital outpatient departments that are enrolled with MassHealth as psychiatric day treatment programs. These services must be provided in compliance with MassHealth's regulations governing psychiatric day treatment program services in 130 CMR 417.000. (See Subchapter 5 of the *Outpatient Hospital Manual* for instructions about obtaining the *Psychiatric Day Treatment Program Manual*, which contains the necessary regulations.)

(C) Acute hospital-based psychiatric day treatment programs are paid according to the outpatient payment methodology established by the signed provider agreement with MassHealth.

(D) Nonacute hospital-based psychiatric day treatment programs are paid according to the outpatient payment methodology established by the Massachusetts Division of Health Care Finance and Policy (DHCFP) (see 130 CMR 410.406).

410.446: Dental Services

(A) MassHealth pays for dental services provided by hospital outpatient departments. These services must be provided in compliance with MassHealth's regulations governing dental services in 130 CMR 420.000. (See Subchapter 5 of the *Outpatient Hospital Manual* for information about obtaining the *Dental Manual*, which contains the necessary regulations.)

(B) Acute hospital-based providers of dental services are paid according to the outpatient payment methodology established by the signed provider agreement with MassHealth.

(C) Nonacute hospital-based providers of dental services are paid according to the outpatient payment methodology established by the DHCFP (see 130 CMR 410.406).

(130 CMR 410.447 through 410.450 Reserved)

410.451: Therapist Services: Covered Services

(A) MassHealth pays for occupational, physical, and speech/language therapy provided in hospital outpatient departments by or under the supervision of licensed therapists. Therapist services include the following:

(1) individual treatment;
(2) comprehensive evaluation;
(3) group therapy; and
(4) design and fitting of an adaptive device.

(B) All therapy must be provided subsequent to a written referral from a licensed physician. MassHealth will pay for continuing physical or occupational therapy only when the physician's referral is renewed in writing every 60 days, subject to the prior-authorization requirements described in 130 CMR 410.408(G).

(C) Before therapy is initiated, a comprehensive evaluation of the member's medical condition, disability, and level of functioning must be performed to determine the need for treatment and, when treatment is indicated, to develop a treatment plan. A comprehensive evaluation must include preparation of a written report for the member's medical record that contains at least the following information:

(1) the member's name and address;
(2) the name of the referring physician;
(3) objective evaluation findings;
(4) a detailed treatment plan prescribing the type, amount, estimated frequency, and duration of therapy and indicating the diagnosis and anticipated goals, or the reason treatment is not indicated;
(5) a description of any conferences with the member, the member's family or physician, or other interested persons;
(6) other health care evaluations, as indicated;
(7) a description of the member's psychosocial and health status that includes:
  (a) the present effects of the disability on both member and family;
  (b) a brief history, the date of onset, and any past treatment of the disability;
  (c) the member's level of functioning, both current and before onset of the disability, if applicable; and
  (d) any other significant physical or mental disability that may affect therapy;
(8) for speech/language therapy only:
  (a) assessments of articulation, stimulability, voice, fluency, and receptive and expressive language;
  (b) a description of the member's cognitive functioning; and
  (c) a description of the member's communication needs and motivation for treatment;
(9) for physical or occupational therapy only: a description of the member's physical limitations; and
(10) the therapist's signature and the date of the evaluation.

(D) The hospital must obtain prior authorization as a prerequisite to payment for certain outpatient therapy services pursuant to 130 CMR 410.408(G).

410.452: Therapist Services: Service Limitations

(A) MassHealth does not pay for performance of a maintenance program. MassHealth pays for designing a maintenance program and instructing the member, member's family, or other persons in its use as part of a regular treatment visit, not as a separate service.

(B) For each type of therapy, MassHealth pays for no more than one individual treatment and one group therapy session for a member per day.

410.453: Therapist Services: Recordkeeping Requirements

In addition to the information required in 130 CMR 410.409, the member's record must include the following:

(A) a licensed physician's written referral for evaluation, referral for treatment, and renewal of referral (if applicable) every 60 days (see 130 CMR 410.451(B));

(B) the written comprehensive evaluation report (see 130 CMR 410.451(C));

(C) the name, address, and telephone number of the member's primary physician;

(D) a treatment notation for each date on which therapy was provided that includes at least the following:
(1) the specific therapeutic procedures and methods used;
(2) the amount of time spent in treatment; and
(3) the signature and title of the person who provided the service;

(E) at least weekly documentation of the following:
(1) the member's response to treatment;
(2) any changes in the member's condition;
(3) the problems encountered or changes in the treatment plan or goals, if any;
(4) the location where the service was provided if different from that in the evaluation report; and
(5) the signature and title of the therapist; and

(F) a discharge summary, when applicable.

(130 CMR 410.454 Reserved)

410.455: Laboratory Services: Introduction

130 CMR 410.455 through 410.459 establish the requirements and procedures for clinical laboratory services provided by hospital outpatient departments. A clinical laboratory service includes the following types of services: microbiological, serological, chemistry, hematological, radioimmunoassay, cytological, immunological, pathological, or other examinations of materials derived from the human body to provide information for the assessment of a medical condition or for the diagnosis, prevention, or treatment of any disease.

410.456: Laboratory Services: Payment

(A) Maximum Allowable Fee.

(1) The maximum allowable payment for an acute hospital outpatient department or hospital-licensed health center laboratory service is the lowest of the following:

(a) the hospital's charge as currently filed with the DHCFP;

(b) the amount described at 42 U.S.C. 1396b(i)(7); or

(c) the usual and customary fee.

(2) The maximum allowable payment for a nonacute hospital outpatient laboratory service is the lowest of the following:

(a) the percentage of charge as established by the DHCFP under 114.1 CMR 28.10;

(b) the amount set by the Medicare fee schedule as described at 42 U.S.C. 1396b(i)(7); or

(c) the usual and customary fee.

(B) Usual and Customary Fee. The term usual and customary means the lowest fee charged by a hospital outpatient department laboratory for any laboratory service (including both individual and profile tests) specified in the hospital outpatient department's charge book or by such hospital, with the exception of a fee offered for a bulk purchase. (A bulk purchase is a single purchase of a laboratory service (one or more tests) to be uniformly and concurrently performed on a minimum of 40 specimens of the same type. A single purchase of various, nonuniform laboratory services, such as by a physician, will not be considered a bulk purchase, regardless of the number of specimens presented by such a purchaser to the hospital outpatient department laboratory.)

(C) Profile or Panel Tests.

(1) A profile or panel test is any group of tests, whether performed manually, automatedly, or semiautomatedly, that is ordered for a specified recipient on a specified day and has at least one of the following characteristics.

(a) The group of tests is designated as a profile or panel by the hospital outpatient department laboratory performing the tests.

(b) The group of tests is performed by the hospital outpatient department laboratory at a usual and customary fee that is lower than the sum of that hospital outpatient department laboratory's usual and customary fees for the individual tests in that group.

(2) In no event shall a hospital outpatient department laboratory bill or be paid separately for each of the tests included in a profile test when a profile test has either been performed by that hospital outpatient department laboratory or requested by an authorized person.

410.457: Laboratory Services: Request for Services

The hospital outpatient department must have either a written requisition or a written order for the laboratory service signed by an authorized prescriber (that is, a licensed physician or dentist, or a registered nurse practitioner) before performing the service. A written requisition signed only by an unauthorized prescriber is not acceptable. Any failure or inability to make the authorized requisition or order available to the Division for review will be sufficient reason to deny or recover payment for all services based on that requisition or order. The hospital outpatient department may send disclosures concerning the test only to the prescriber, to the referring laboratory, if applicable, to the Division, and, at the written request of the prescriber, to the recipient.

410.458: Laboratory Services: Recordkeeping Requirements

In addition to meeting the recordkeeping requirements specified in 130 CMR 410.409, the hospital outpatient department must keep a suitable record of each specimen and laboratory test result for at least six years from the date on which the results were reported to the prescriber. Such a record must contain the following information:

(A) the name and any other means of identification of the person from whom the specimen was taken;

(B) the name of the prescriber or laboratory that submitted the specimen;

(C) the authorized requisition or order, or both;

(D) the location where the specimen was taken, if other than the hospital outpatient department;

(E) the date on which the specimen was collected by the prescriber or laboratory;

(F) the date on which the specimen was received in the laboratory;

(G) the condition of unsatisfactory specimens when received (for example, broken, leaked, hemolyzed, turbid, or insufficient sample size);

(H) the date on which the test was performed;

(I) the test name and the results of the test, or the cross-reference to results and the date of reporting; and

(J) the name and address of the laboratory to which the specimen was referred, if applicable.

410.459: Laboratory Services: Specimen Referral

A hospital outpatient department may refer a specimen to an independent laboratory that is eligible to participate in the Medical Assistance Program, or to another hospital laboratory that is eligible to participate in the Medical Assistance Program. To be eligible, a hospital laboratory must be in a hospital that is licensed by the Massachusetts Department of Public Health and that is an approved Medicare provider. The referring hospital outpatient department laboratory must inform the prescriber of the name and address of the testing laboratory. The testing laboratory must inform the referring hospital outpatient department laboratory of the results of the test. Only the referring laboratory is authorized to bill the Division.

(l06 CMR 410.460 Reserved)

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410.461: Pharmacy Services: Prescription Requirements

(A) Legal Prescription Requirements. The Division pays for legend drugs, nonlegend drugs, and those medical supplies listed at 130 CMR 410.462(C) only if the pharmacy has in its possession a prescription that meets all requirements for a legal prescription under all applicable federal and state laws and regulations. Each prescription, regardless of drug schedule, must contain the prescriber's unique DEA number. For Schedule VI drugs, if the prescriber has no DEA registration number, the prescriber must provide the state registration number on the prescription.

(B) Emergencies. When the pharmacy determines that an emergency exists, the Division will authorize a pharmacy to dispense at least a 72-hour, nonrefillable supply of the drug in compliance with state and federal regulations.

(C) Refills.

(1) The Division does not pay for prescription refills that exceed the specific number authorized by the prescriber.

(2) The Division pays for a maximum of five monthly refills.

(3) The Division pays for more than five refills within a six-month period if such refills are for less than a 30-day supply and have been prescribed and dispensed in accordance with 130 CMR 410.461(D).

(4) The Division does not pay for any refill dispensed after six months from the date of the original prescription.

(5) The absence of an indication to refill by the prescriber renders the prescription nonrefillable.

(D) Quantities.

(1) Days' Supply Limitations. The Division requires that all drugs be prescribed and dispensed in at least a 30-day supply, but no more than a 90-day supply, unless the drug is available only in a larger minimum package size, except as specified in 130 CMR 410.461(D)(2).

(2) Exceptions to Days' Supply Limitations. The Division allows exceptions to the limitations described in 130 CMR 410.461(D)(1) for the following products:

(a) drugs in therapeutic classes that are commonly prescribed for less than a 30-day supply, including but not limited to antibiotics and analgesics;

(b) drugs that, in the prescriber's professional judgement, are not clinically appropriate for the member in a 30-day supply;.

(c) drugs that are new to the member, and are being prescribed for a limited trial amount, sufficient to determine if there is an allergic or adverse reaction or lack of effectiveness. The initial trial amount and the member's reaction or lack of effectiveness must be documented in the member's medical record;

(d) drugs packed in such a way that the smallest quantity that may be dispensed is larger than a 90-day supply (for example, inhalers, ampules, vials, eye drops, and other sealed containers not intended by the manufacturer to be opened by any person other than the end user of the product);

(e) drugs in topical dosage forms that do not allow the pharmacist to accurately predict the rate of the product's usage (for example, lotions or ointments); and

(f) products generally dispensed in the original manufacturer's packaging (for example, fluoride preparations, prenatal vitamins, and over-the-counter drugs).

(E) Prescription-Splitting. Providers must not split prescriptions by filling them for a period or quantity less than that specified by the provider. For example, a prescription written for a single 30-day supply may not be split into three 10-day supplies. The Division considers prescription-splitting to be fraudulent. (See 130 CMR 450.238(B)(6).)

410.462: Pharmacy Services: Covered Drugs and Medical Supplies for MassHealth Members

(A) Drugs. The MassHealth Drug List specifies the drugs that are payable under MassHealth.
(1) Legend Drugs. The Division pays only for legend drugs that are approved by the U.S. Food and Drug Administration and manufactured by companies that have signed rebate agreements with the U.S. Secretary of Health and Human Services pursuant to 42 U.S.C. 1396r-8.
(2) Nonlegend Drugs. The Division pays only for the nonlegend drugs listed in Appendix M of the *Outpatient Hospital Manual* (Nonlegend Drug List).

(B) Medical Supplies. The Division pays only for the medical supplies listed below:
(1) blood and urine testing reagent strips used for the management of diabetes;
(2) disposable insulin syringe and needle units;
(3) insulin cartridge delivery devices and needles (for example, pens);
(4) lancets; and
(5) drug delivery systems for use with metered dose inhalers (for example, aerochambers).

410.463: Pharmacy Services: Limitations on Coverage of Drugs

(A) Interchangeable Drug Products. The Division pays no more for a brand-name interchangeable drug product than its generic equivalent, unless:
(1) the prescriber has requested and received prior authorization from the Division for a nongeneric multiple-source drug (see 130 CMR 410.408); and
(2) the prescriber has written on the face of the prescription in the prescriber's own handwriting the words "brand name medically necessary" under the words "no substitution" in a manner consistent with applicable state law. These words must be written out in full and may not be abbreviated.

(B) Drug Exclusions. The Division does not pay for the following types of drugs or drug therapy:

(1) Cosmetic. The Division does not pay for legend or nonlegend preparations for cosmetic purposes or for hair growth.

(2) Cough and Cold. The Division does not pay for legend or nonlegend preparations that contain an antitussive or expectorant as a major ingredient, or any drug used solely for the symptomatic relief of coughs and colds, when they are dispensed to a noninstitutionalized member.

(3) Fertility. The Division does not pay for any drug used to promote male or female fertility.

(4) Obesity Management. The Division does not pay for any drug used for the treatment of obesity.

(5) Smoking Cessation. The Division does not pay for any drug used for smoking cessation.

(6) Less-Than-Effective Drugs. The Division does not pay for drug products (including identical, similar, or related drug products) that the U.S. Food and Drug Administration has proposed, in a Notice of Opportunity for Hearing (NOOH), to withdraw from the market because they lack substantial evidence of effectiveness for all labeled indications.

(7) Experimental and Investigational Drugs. The Division does not pay for any drug that is experimental, medically unproven, or investigational in nature.

(C) Service Limitations.

(1) The Division covers drugs that are not explicitly excluded under 130 CMR 420.418(B). The MassHealth Drug List specifies the drugs that are payable under MassHealth. Any drug that does not appear on the MassHealth Drug List requires prior authorization, as set forth in 130 CMR 420.000. The MassHealth Drug List can be viewed on the Division's Web site, and copies may be obtained upon request. The Division will evaluate the prior-authorization status of drugs on an ongoing basis, and update the MassHealth Drug List accordingly. See 130 CMR 450.303.

(2) The Division does not pay for the following types of drugs or drug therapy without prior authorization:

(a) immunizing biologicals and tubercular (TB) drugs that are available free of charge through local boards of public health or through the Massachusetts Department of Public Health (DPH); (b) nongeneric multiple-source drugs;

(c) drugs used for the treatment of male or female sexual dysfunction;

(d) drugs related to sex-reassignment surgery, specifically including but not limited to, presurgery and postsurgery hormone therapy. The Division, however, will continue to pay for post sex-reassignment surgery hormone therapy for which it had been paying immediately prior to May 15, 1993; and

(e) retinoids for members aged 26 or older. The Division pays for retinoids for members under age 26, and all other topical acne products for members of all ages who have cases of acne Grade II or higher, without prior authorization.

(3) The Division does not pay any additional fees for dispensing drugs in a unit-dose distribution system.

(4) The Division does not pay for any drug prescribed for other than the FDA-approved indications as listed in the package insert, except as the Division determines to be consistent with current medical evidence.

(D) Insurance Coverage.

(1) Managed Care Organizations. The Division does not pay pharmacy claims for services to MassHealth members enrolled in a MassHealth managed care organization (MCO) that provides pharmacy coverage through a pharmacy network or otherwise, except for family planning pharmacy services provided by a non-network provider to a MassHealth Standard MCO enrollee (where such provider otherwise meets all prerequisites for payment for such services). A pharmacy that does not participate in the MassHealth member's MCO must instruct the MassHealth member to take his or her prescription to a pharmacy that does participate in such MCO. To determine whether the MassHealth member belongs to an MCO, pharmacies must verify member eligibility and scope of services through POPS before providing service in accordance with 130 CMR 450.107 and 450.117.

(2) Other Health Insurance. When the member's primary carrier has a preferred drug list, the prescriber must follow the rules of the primary carrier first. The provider may bill the Division for the primary insurer's copayment for the primary carrier's preferred drug without regard to whether the Division generally requires prior authorization, except in cases where the drug is subject to a pharmacy service limitation pursuant to 130 CMR410.463(C)(2)(a), (c), (d), and (e). In such cases, the prescriber must obtain prior authorization from the Division in order for the pharmacy to bill the Division for the primary insurer's copayment.

410.464: Pharmacy Services: Drugs and Medical Supplies Provided by Hospital-Based Pharmacies

Drugs and medical supplies provided by hospital-based pharmacies must be provided and billed in accordance with the Division's regulations governing pharmacy services in 130 CMR 406.000.

410.465: Pharmacy Services: Drugs and Medical Supplies for Members in Institutions

(A) The Division does not pay for nonlegend drugs or medical supplies provided to an institutionalized member.

(B) The Division pays for legend drugs and ostomy supplies provided to an institutionalized member.

410.466: Pharmacy Services: Prior Authorization

(A) Prescribers must obtain prior authorization from the Division for drugs identified by the Division in accordance with 130 CMR 450.303. If the limitations on covered drugs specified in 130 CMR 410.462(A)(1) and 410.463(A) and (C) would result in inadequate treatment for a diagnosed medical condition, the prescriber may submit a written request, including written documentation of medical necessity, to the Division for prior authorization for an otherwise noncovered drug.

(B) All prior-authorization requests must be submitted in accordance with the instructions in Subchapter 5 of the *Outpatient Hospital Manual*. If the Division approves the request, it will notify both the pharmacy and the member.

(C) The Division will authorize at least a 72-hour emergency supply of a prescription drug to the extent required by federal law. (See 42 U.S.C. 1396r-8(d)(5).) The Division acts on requests for prior authorization for a prescribed drug within a time period consistent with federal regulations.

(D) Prior authorization does not waive any other prerequisites to payment such as, but not limited to, member eligibility or requirements from other health insurers.

(E) The MassHealth Drug List specifies the drugs that are payable under MassHealth. Any drug that does not appear on the MassHealth Drug List requires prior authorization, as set forth in 130 CMR 410.461 through 410.466. The Division will evaluation the prior-authorization status of drugs on an ongoing basis, and update the MassHealth Drug List.

410.467: Pharmacy Services: Member Copayments

Under certain conditions, the Division requires that members make a copayment to the dispensing pharmacy for each original prescription and for each refill for all drugs (whether legend or nonlegend) covered by MassHealth. The copayment requirements are detailed in the Division's administrative and billing regulations at 130 CMR 450.130.

(130 CMR 410.468 through 410.470 Reserved)

410.471: Mental Health Services: Introduction

A mental health program is a comprehensive group of diagnostic and treatment services, as outlined in 130 CMR 410.474, furnished to mentally or emotionally disabled persons and their families under the direction of a licensed psychiatrist. The Division pays for mental health services provided in hospital outpatient departments subject to the restrictions and limitations in 130 CMR 410.472 through 410.479.

410.472: Mental Health Services: Noncovered Services

(A) Nonmedical Services. The Division does not pay for nonmedical mental health services. These services include, but are not limited to, the following:

(1) vocational rehabilitation services;
(2) sheltered workshops;
(3) educational services;
(4) recreational services (play therapy, the use of play activities with a child in an identified treatment setting as an alternative to strictly verbal expression of conflicts and feelings, is not considered a recreational service and is covered);
(5) life-enrichment services (ego-enhancing services such as workshops or educational courses provided to functioning persons); and
(6) telephone conversations.

(B) Nonmedical Programs. The Division does not pay for diagnostic and treatment services that are provided as an integral part of a planned and comprehensive program that is organized to provide primarily nonmedical or other nonreimbursable services. Such programs include alcohol or drug drop-in centers.

(130 CMR 410.473 Reserved)

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410.474: Mental Health Services: Definitions

The following terms used in 130 CMR 410.471 through 410.479 shall have the meanings given in 130 CMR 410.474 unless the context clearly requires a different meaning. When provided in a hospital outpatient department, services that are defined below must conform to the definitions given.

(A) Diagnostic Services -- the examination and determination of a patient's physical, psychological, social, economic, educational, and vocational assets and disabilities for the purpose of designing a treatment plan.

(B) Psychological Testing -- the use of standardized test instruments to evaluate aspects of an individual's functioning, including aptitudes, educational achievements, cognitive processes, emotional conflicts, and type and degree of psychopathology, subject to the limitations of 130 CMR 410.479(H).

(C) Long-Term Therapy -- a combination of diagnostics and individual, couple, family, and group therapy planned to last more than 17 sessions.

(D) Short-Term Therapy -- a combination of diagnostics and individual, couple, family, and group therapy planned to end within 17 sessions.

(E) Individual Therapy -- therapeutic services provided to an individual.

(F) Couple Therapy -- therapeutic services provided to a couple whose primary complaint is the disruption of their marriage, family, or relationship.

(G) Family Therapy -- the treatment of more than one member of a family simultaneously in the same session.

(H) Group Therapy -- the application of psychotherapeutic or counseling techniques to a group of persons, most of whom are not related by blood, marriage, or legal guardianship.

(I) Medication Visit -- a recipient visit specifically for prescription, review, and monitoring of medication by a psychiatrist or administration of prescribed intramuscular medication by qualified personnel.

(J) Case Consultation -- a preplanned meeting of at least one-half hour's duration concerning a recipient who is either:

(1) a client of the hospital outpatient department to whom it is the primary provider of therapeutic services; or

(2) one for whom evaluation and assessment have been requested by another agency or program involved in treatment or management of the recipient.

(K) Family Consultation -- a preplanned meeting with the parent or parents of a child who is being treated, when the parent or parents are not clients.

(L) Crisis Intervention/Emergency Services -- immediate mental health evaluation, diagnosis, hospital prescreening, treatment, and arrangements for further care and assistance as required, provided during all hours to clients showing sudden, incapacitating emotional stress. The Division will pay only for face-to-face contact; telephone contacts are not reimbursable.

(M) Home Visit -- crisis intervention, individual, group, or family therapy, and medication provided in the recipient's residence (excluding a medical institution), when the recipient is unable to be served at the hospital outpatient department.

410.475: Mental Health Services: Staffing Requirements

(A) Provider Responsibilities.
(1) The hospital outpatient department must employ a balanced interdisciplinary staff to furnish mental health services under the direction of a licensed psychiatrist.
(2) The hospital outpatient department must designate a professional staff member as director of clinical services and a licensed psychiatrist as medical director.
(3) A licensed psychiatrist must be on call during all hours of operation.
(4) Although the Division does not require that the hospital outpatient department employ mental health professionals from all the disciplines listed in 130 CMR 410.475(B), staff members who provide services to recipients must be qualified as set forth in 130 CMR 410.475(B) for their respective disciplines.

(B) Staff Qualifications.
(1) Psychiatrist. At least one staff psychiatrist must be either currently certified by the American Board of Psychiatry and Neurology or eligible for such certification. Any additional psychiatrists must be, at the minimum, licensed physicians in their second year of a psychiatric residency program accredited by the Council on Medical Education of the American Medical Association. Such physicians must be under the direct supervision of a licensed psychiatrist.
(2) Psychologist. At least one staff psychologist must be licensed by the Massachusetts Board of Registration of Psychologists with a specialization listed in clinical or counseling psychology or a closely related specialty. Additional staff members trained in the field of clinical or counseling psychology or a closely related specialty must:
(a) have a minimum of a master's degree or the equivalent graduate study in clinical or counseling psychology or a closely related specialty from an accredited educational institution;
(b) be currently enrolled in or have completed a doctoral program in clinical or counseling psychology or a closely related specialty; and
(c) have had two years of full-time supervised clinical experience subsequent to obtaining a master's degree in a multidisciplinary mental health setting. (One year of supervised clinical work in an organized graduate internship program may be substituted for each year of experience.)

(3) Social Worker.

(a) At least one staff social worker must be licensed or have applied for and have a license pending as an independent clinical social worker by the Massachusetts Board of Registration of Social Workers.

(b) Any additional social workers on the staff must provide services under the direct and continuous supervision of an independent clinical social worker. Such additional social workers must be licensed or applying for licensure as certified social workers by the Massachusetts Board of Registration of Social Workers and have received a master's degree in social work and completed two years of full-time supervised clinical work in an organized graduate internship program.

(4) Psychiatric Nurse. At least one psychiatric nurse must be currently registered by the Massachusetts Board of Registration in Nursing and must have a master's degree in nursing from an accredited National League of Nursing graduate school with two years of full-time supervised clinical experience in a multidisciplinary mental health setting and be eligible for certification as a clinical specialist in psychiatric/mental health nursing by the American Nursing Association. Any other nurses must have a bachelor's degree from an educational institution accredited by the National League of Nursing and two years of full-time supervised skilled experience in a multidisciplinary mental health setting subsequent to that degree, or a master's degree in psychiatric nursing.

(5) Counselor. A counselor must have a master's degree in counseling education, counseling psychology, or rehabilitation counseling from an accredited educational institution and two years of full-time supervised clinical experience in a multidisciplinary mental health setting subsequent to obtaining the master's degree. (One year of supervised clinical work in an organized graduate internship program may be substituted for each year of full-time experience.)

(6) Occupational Therapist. An occupational therapist must be currently licensed by the Massachusetts Division of Registration of Allied Health Professions and registered by the American Occupational Therapy Association and must have either:

(a) a master's degree in occupational therapy from an accredited program in occupational therapy; or

(b) a bachelor's degree in occupational therapy from an accredited program in occupational therapy and a master's degree in a related field such as psychology, social work, or counseling.

410.476: Mental Health Services: Treatment Procedures

(A) A professional staff member must conduct a comprehensive evaluation of each recipient prior to initiation of therapy.

(B) The hospital outpatient department must accept for treatment, refer for treatment elsewhere, or both, any recipient for whom the intake evaluation substantiates a mental or emotional disorder.

(C) One professional staff member (the primary therapist) shall assume primary responsibility for each recipient. This responsibility shall include:

(1) within four client visits, preparation of a comprehensive written treatment plan that is based on the initial evaluation, incorporates short- and long-term treatment goals, and establishes criteria for determining when termination of treatment is appropriate;

(2) ongoing utilization review; and

(3) review of each case at termination of treatment and preparation of a termination summary that describes the course of treatment and any aftercare program or resources in which the recipient is expected to participate.

(D) The hospital outpatient department shall make provisions for responding to persons needing services on a walk-in basis.

(E) The hospital outpatient department shall take appropriate steps to facilitate uninterrupted and coordinated recipient care whenever it refers a recipient elsewhere for concurrent or subsequent treatment.

(F) Before referring a recipient elsewhere, the hospital outpatient department shall, with the recipient's consent, send a summary of or the actual record of the recipient to that referral provider.

410.477: Mental Health Services: Utilization Review Plan

A mental health program must have a utilization review plan that is acceptable to the Division and that meets the following conditions.

(A) A utilization review committee is to be formed, composed of the clinical director (or a designee), a psychiatrist, and one other professional staff member from each core discipline represented who meets all the qualifications for the discipline, as outlined in 130 CMR 410.475.

(B) The utilization review committee is to review a representative sample of cases at least in the following circumstances:

(1) within 90 days after initial contact;

(2) when a recipient has required more than 50 visits every 12 months and has not required hospitalization or extensive crisis intervention during that period; and

(3) following termination.

(C) The utilization review committee is to verify for a representative sample of cases that:
(1) the diagnosis has been adequately documented;
(2) the treatment plan is appropriate and specifies the methods and duration of the projected treatment program;
(3) the treatment plan is being or has been carried out;
(4) the treatment plan is being or has been modified as indicated by the recipient's changing status;
(5) there is adequate follow-up when a recipient misses appointments or drops out of treatment; and
(6) there is progress toward achievement of short- and long-term goals.

(D) No staff member is to participate in the utilization review committee's deliberations about any recipient that staff member is treating directly.

(E) The program is to maintain minutes that are sufficiently detailed to show the decisions of each review and the basis on which any decisions are made so that the Division may conduct such audits as it deems necessary.

(F) Based on the utilization review, the director of clinical services or a designee is to determine whether continuation, modification, or termination of treatment is necessary and promptly communicate this decision to the primary therapist.

410.478: Mental Health Services: Recordkeeping Requirements

(A) The hospital outpatient department must obtain, upon the initiation of treatment, written authorization from each recipient or the recipient's legal guardian to release information obtained by the provider to hospital staff, federal and state regulatory agencies, and, when applicable, referral providers, to the extent necessary to carry out the purposes of the program and to meet regulatory requirements, including provider audits.

(B) In addition to the information required in 130 CMR 410.409, each recipient's record must include the following information:
(1) the recipient's case number, address, telephone number, sex, age, marital status, next of kin, and school or employment status (or both);
(2) the date of initial contact and, if applicable, the referral source;
(3) a report of a physical examination performed within six months (if such an examination has not been performed in that period, one must be given within 30 days after the recipient's request for services or, if the recipient refuses to be examined, the record must document the reasons for the exam postponement);
(4) the name and address of the recipient's primary physician or medical clinic (a physician or medical clinic must be recommended if there is not one currently attending the recipient);

(5) a description of the nature of the recipient's condition;
(6) the relevant medical, social, educational, and vocational history;
(7) a comprehensive functional assessment of the recipient;
(8) the clinical impression of the recipient and a diagnostic formulation, including a specific diagnosis using ICD-9-CM or DSM III diagnosis codes;
(9) the recipient's treatment plan, updated as necessary, including long-range goals, short-term objectives, and the proposed schedule of therapeutic activities;
(10) a schedule of dates for utilization review to determine the recipient's progress in accomplishing goals and objectives;
(11) the name, qualifications, and discipline of the primary therapist;
(12) a written record of utilization reviews by the primary therapist;
(13) documentation of each visit, including the recipient's response to treatment, written and signed by the person providing the service, and including the therapist's discipline and degree;
(14) all information and correspondence regarding the recipient, including appropriately signed and dated consent forms;
(15) a medication-use profile; and
(16) when the recipient is discharged, a discharge summary.

(C) A brief history is acceptable for emergency or walk-in visits when the treatment plan does not call for extended care.

410.479: Mental Health Services: Service Limitations

(A) Length and Frequency of Sessions.
(1) The Division will pay for diagnostic and treatment services only when a professional staff member personally provides these services to the recipient or the recipient's family, or personally consults with a professional outside of the hospital outpatient department. The services must be provided to the recipient on an individual basis.
(2) The Division will pay for only one session of the types of services listed in 130 CMR 410.479(C) through (H) provided to an individual recipient on one date of service. Return visits on the same date of service are not reimbursable.

(B) Diagnostic Services. Payment for diagnostic services provided to a recipient is limited to a maximum of four hours or eight units.

(C) Individual Therapy. Payment for individual therapy is limited to a maximum of one hour per session per day.

(D) Family Therapy.

(1) Payment for family therapy is limited to a maximum of one-and-one-half hours per session per day.

(2) Payment shall also be limited to one payment per family therapy visit, regardless of the number of staff members or recipients who are present.

(E) Case Consultation.

(1) The Division will pay only for case consultation that lasts at least 30 minutes and involves a personal meeting with a professional of another agency. Payment is limited to a maximum of one hour per session.

(2) The Division will pay for case consultation only when telephone contact, written communication, and other nonreimbursable forms of communication clearly will not suffice. Such circumstances must be documented in the recipient's record and also in the prior authorization request, if applicable. Such circumstances are limited to situations in which both the hospital outpatient department and the other party are actively involved in treatment or management programs with the recipient (or family members) and where a lack of face-to-face communication would impede a coordinated treatment program.

(3) The Division will not pay for court testimony.

(F) Family Consultation. The Division will pay for consultation with the natural or foster parent or legal guardian of a recipient less than 21 years of age who lives with the child, is responsible for the child's care, and is not an eligible recipient, when such consultation is integral to the treatment of the recipient.

(G) Group Therapy.

(1) The Division will pay only for a group therapy session that has a minimum duration of one and one-half hours and a maximum duration of two hours.

(2) Payment is limited to one fee per group member with a maximum of 10 recipients per group regardless of the number of staff members present.

(3) The Division will not pay for group therapy when it is performed as an integral part of a psychiatric day treatment program.

(H) Psychological Testing. The Division will pay for psychological testing only when the following conditions are met.

(1) A psychologist who is licensed by the Massachusetts Board of Registration of Psychologists with a specialization listed in clinical or counseling psychology or a closely related specialty either personally administers the testing or personally supervises such testing during its administration by an unlicensed psychologist.

(2) A battery of tests is performed. These tests must meet the following standards:

(a) the tests are published, valid, and in general use, as evidenced by their presence in the current edition of the Mental Measurement Yearbook or by their conformity to the Standards for Educational and Psychological Tests of the American Psychological Association;
(b) a personality evaluation contains the findings of at least two of the following test types or their age-appropriate equivalents: Rorschach, TAT (Thematic Apperception Test), TED (Tasks of Emotional Development), or MMPI (Minnesota Multiphasic Personality Inventory), and one or more of the following test types: figure drawing, Bender-Gestalt, or word association;
(c) intelligence testing includes either a full Wechsler or Stanford-Binet instrument or an equivalent; and
(d) assessment of brain damage contains at least the findings of a Wechsler Intelligence Scale and tests of recent memory, visual-space perception, and other functions commonly associated with brain damage.

(3) Except as explained below, the Division will not pay for:
(a) self-rating forms and other paper-and-pencil instruments, unless administered as part of a comprehensive battery of tests;
(b) group forms of intelligence tests;
(c) an intelligence test performed at the same time as a brain assessment;
(d) short-form, abbreviated, or "quick" intelligence tests administered at the same time as the Wechsler or Stanford-Binet tests; otherwise, such tests are reimbursable only at a lower rate than standard intelligence tests on an individual consideration basis; or
(e) a repetition of any psychological test or tests provided to the same recipient within the preceding six months, unless accompanied by documentation demonstrating that the purpose of the repeated testing is to ascertain changes following such special forms of treatment or intervention as electroshock therapy or psychiatric hospitalization (periodic testing to measure the recipient's response to psychotherapy is not reimbursable); or relating to suicidal, homicidal, toxic, traumatic, or neurological conditions. Submission of such documentation with the claim for payment is sufficient when the psychological test or tests are to be performed on the same recipient a second time within a six-month period. Further repetitions will be paid for by the Division only if this documentation is submitted and prior authorization granted by the Division prior to the testing (see 130 CMR 410.473).

(4) Testing of a recipient requested by responsible parties, such as but not limited to physicians, clinics, hospitals, schools, courts, group homes, or state agencies, must be documented in the recipient's record. Such documentation must include the referral source and the reason for the referral.

(I) Medication Visits. The Division will not pay for a medication visit as a separate service when it is performed as part of another treatment service (for example, a diagnostic assessment or individual or group therapy performed by a psychiatrist).

(J) Home Visits.

(1) The Division will pay for intermittent home visits. Payment will also be made for home visits made for diagnostic purposes.

(2) Home visits are reimbursable on the same basis as comparable services provided at the hospital outpatient department. Travel time to and from the recipient's home is not reimbursable.

(3) A report of the home visit must be entered into the recipient's record.

(K) Multiple Therapies. The Division will pay for more than one mode of therapy used for a recipient during one week only if clinically justified; that is, when any single approach has been shown to be necessary but insufficient. The need for additional modes of treatment should be documented in the recipient's record.

(L) Outreach Services Provided in Nursing Facilities. The Division will pay for diagnostic and treatment services provided in a nursing facility to a recipient who resides in that nursing facility only in the following circumstances:

(1) the nursing facility specifically requests treatment and the recipient's record at the nursing facility documents this request;

(2) the treatment provided does not duplicate services usually provided in the nursing facility;

(3) such services are generally available through the hospital outpatient department to recipients not residing in that nursing facility; and

(4) the recipient either cannot leave the nursing facility or is sufficiently mentally or physically incapacitated to be unable to come to the hospital outpatient department alone.

(130 CMR 410.480 Reserved)

410.481: Vision Care Services: General Requirements

(A) Introduction.

(1) The regulations in 130 CMR 410.481 through 410.489 establish the requirements and procedures for vision care services provided by hospital outpatient departments. Vision care services are the professional care of the eyes for purposes of diagnosing and correcting refractive errors, analyzing muscular anomalies, and determining pathological conditions. They include eye examinations, vision training, and the prescription and dispensing of ophthalmic materials. Professional and technical services shall be provided in accordance with the established standards of quality and health care necessity recognized by the vision care industry and licensing agencies in Massachusetts.

(2) The Division covers the following services only when provided to eligible MassHealth members under age 21: ophthalmic materials, specifically including, but not limited to, complete eyeglasses or eyeglass parts; the dispensing of ophthalmic materials; contact lenses; and other visual aids, except that this age limitation does not apply to visual magnifying aids for use by members who are both diabetic and legally blind. Visual magnifying aids do not include eyeglasses or contact lenses.

(B) Definitions. The following terms used in 130 CMR 410.481 through 410.489 shall have the meanings given in 130 CMR 410.481 unless the context clearly requires a different meaning.

(1) Dispensing Practitioner -- any optician, optometrist, ophthalmologist, or other participating provider authorized by the Division to dispense eyeglass frames, lenses, and other vision care materials to recipients.

(2) Optical Supplier -- the optical laboratory contracted by the Division to supply the following ophthalmic materials and services:

(a) eyeglass frames;
(b) eyeglass lenses;
(c) frame cases;
(d) tints, coatings, ground-on prisms, and prisms by decentration; and
(e) repair parts.

(3) Order -- the process by which a dispensing practitioner requests ophthalmic materials (completed eyeglasses, repair parts, and other services) from the optical supplier.

(4) Order Form -- the form used by the dispensing practitioner to request ophthalmic materials (completed eyeglasses, repair parts, and other services) from the optical supplier. The required form is specified in the billing instructions in Subchapter 5 of the *Outpatient Hospital Manual*.

(5) Prescriber -- any optometrist, ophthalmologist, or other practitioner licensed and authorized to write prescriptions for eyeglass frames, lenses, and other vision care services.

(C) Nonreimbursable Circumstances. Vision care services are not reimbursable to a vision care provider when the services were furnished in a state institution, in an inpatient hospital, or in a hospital-affiliated teaching institution, and when the services are among those for which the provider is compensated by the state or institution.

(D) Prior Authorization.

(1) For certain vision care services specified in 130 CMR 410.484 through 410.487, the Division requires the provider to obtain prior authorization as a prerequisite to payment.

(2) All prior authorization requests must be submitted in accordance with the instructions in Subchapter 5 of the *Outpatient Hospital Manual*.

410.482: Vision Care Services: Prescription and Dispensing Requirements

(A) Eyeglasses and other visual aids may be dispensed only upon a written and dated prescription. The prescription must be based upon the results of a vision examination performed by the prescriber. The prescription must include all information that is necessary to enable a dispensing practitioner to order the prescription.

(B) The prescriber must provide the recipient with a signed copy of the prescription without extra charge. The date or dates on which the prescription is filled or refilled must be recorded on the recipient's copy of the prescription.

(C) The prescriber may order the prescription or may refer the recipient to another vision care provider.

(D) For a dispensing practitioner to be paid for dispensing a prescription involving ophthalmic materials and services available through the optical supplier, all such materials and services must be ordered from the optical supplier. These ophthalmic materials include a specific selection of eyeglass frames for men, women, and children. When eyeglasses are being ordered, recipients must choose from this selection of frames. Information describing all of the ophthalmic materials and services furnished by the optical supplier is published by the optical supplier under the title "Vision Care Materials" and is distributed to vision care providers by the Division.

(E) To receive payment for dispensing an item, the dispensing practitioner must take all necessary measurements, verify lens characteristics, and adjust the completed appliance to the individual. At no additional charge, the dispensing practitioner must continue to make necessary adjustments to the completed appliance for six months after the dispensing date.

(F) The optical supplier will replace free of charge any lens containing any defect or error caused by the optical supplier. Such defects or errors include lenses that are broken, scratched, or chipped at the time of receipt by the dispensing practitioner, or lenses that deviate from the dispensing practitioner's prescription beyond the deviation standards permitted in the American National Standards Institute Z80 rulings. This provision will be effective only if the defective or incorrect lens is received by the optical supplier from the dispensing practitioner within seven working days after the date on which the optical supplier sent the completed order to the dispensing practitioner, and only if it is accompanied by a copy of the original order form containing a notation of the defect or error. In the event of a dispute between the optical supplier and a dispensing practitioner regarding lens deviation, the Division will determine whether the lens in dispute exceeds deviation standards.

(G) Although contractual arrangements are in effect between the Division and the optical supplier, all regulations regarding reimbursable and nonreimbursable services, including prior authorization requirements, are applicable to all dispensing practitioners.

(H) An order to the optical supplier for prescribed items shall constitute a representation by the dispensing practitioner that the person for whom the prescribed item is ordered is an eligible recipient as of the date of the order. Payment to the optical supplier for items provided pursuant to an order from the dispensing practitioner shall be chargeable to the dispensing practitioner when the practitioner failed to ascertain recipient eligibility in accordance with 130 CMR 450.000 and with the service limitations in 130 CMR 410.484 through 410.487.

410.483: Vision Care Services: Recordkeeping Requirements

(A) A vision care provider must maintain a suitable health care record for each recipient. The record must fully disclose all pertinent information regarding the services furnished, including the date of service, the dates on which materials were ordered and dispensed, and a description of materials (including the frame style and the manufacturer's name) ordered and dispensed. All health care findings resulting from a visual analysis, whether they are normal or abnormal, must be recorded. When extenuating circumstances prevent the use of one or more procedures normally done in a visual analysis, the record must contain the reasons that the tests were not performed.

(B) For comprehensive eye examinations and diagnoses, the record must contain the following information or test results:

(1) case history;
(2) visual acuity testing;
(3) ophthalmoscopy and external eye health examination;
(4) ocular mobility testing, heterophoria testing, and fusion testing;
(5) pupillary reflex testing;
(6) refraction (retinoscopy, subjective refraction, and keratometry);
(7) confrontation fields or other screening tests;
(8) tonometry, when medically indicated;
(9) case analysis and disposition; and
(10) biomicroscopy, when medically indicated.

(C) All consultation services must be fully documented in the record. A record for a consultation must contain the following information:

(1) the recipient's complaints and symptoms;
(2) the condition of the eye; and
(3) if applicable, the name of the person to whom a referral was made.

(D) All screening services must be fully documented in the record. A record for a screening service must note the chief complaint and must contain all findings of two or more of the following tests:

(1) visual acuity;
(2) distance vision and near vision;
(3) cover test;
(4) visual skills;
(5) tonometry; and
(6) biomicroscopy.

410.484: Vision Care Service Limitations: Visual Analysis

(A) The Division will not pay for a comprehensive eye examination or a visual analysis if either has been furnished:
(1) within the preceding 12 months, for a recipient under the age of 21; or
(2) within the preceding 24 months, for a recipient aged 21 or older.
However, these restrictions do not apply if there is a referral from the recipient's physician or if one of the following complaints or conditions is documented in the recipient's record: blurred vision, evidence of headaches, diabetes, or cataracts.

(B) The Division will pay for a consultation service only if it is provided independently of a comprehensive eye examination.

(C) The Division will not pay for a screening service if two screening services have been furnished to the recipient within the preceding 12 months.

(D) A comprehensive eye examination includes a screening service. If the provider performs both a screening service and a comprehensive eye examination for the same recipient, the Division will pay for only the latter.

(E) The Division will not pay for a tonometry as a separate service when it is performed as part of a comprehensive eye examination, a consultation, or a screening service. However, a tonometry is reimbursable when performed as a separate service to monitor a recipient who has glaucoma.

410.485: Vision Care Service Limitations: Dispensing Eyeglasses

(A) Time and Power Restrictions.
(1) The Division will pay for only one initial pair of eyeglasses and only if there is a corrective power of at least " .75D sphere or " .50D cylinder. (See 130 CMR 410.487(B) for an exception permitting two pairs of eyeglasses instead of bifocals.)
(2) The Division will pay for the replacement of a pair of lost or stolen eyeglasses only if there is a corrective power of at least " .75D sphere or " .50D cylinder, and only if the lost or stolen eyeglasses were not dispensed within the preceding 18 months.

(3) The Division will pay for a subsequent pair of eyeglasses only if there is a change from the current prescription of at least ± .50D sphere or cylinder; or an axis change of at least 3° for a ± 1.00D cylinder or over, 5°for a ± .75D cylinder, or 10° for a ± .50D cylinder.

(B) Broken Eyeglasses. The Division will pay for the repair of broken eyeglasses, including the replacement of broken parts, subject to the following limitations.

(1) No serviceable parts of eyeglass frames supplied by the optical supplier shall be replaced.

(2) Except for recipients under the age of 21, the Division will not pay for the replacement of broken frames and lenses if a repair of either broken frames or lenses was furnished within the preceding 18 months.

(3) Dispensing practitioners must order replacement eyeglass frames, lenses, and repair parts from the optical supplier. Dispensing practitioners must use the order form to obtain replacement parts.

(4) When there is damage to eyeglass frames or lenses that were not fabricated by the optical supplier, dispensing practitioners must adhere to the following procedure:

(a) the recipient must be instructed to choose a new frame from the selection available through the Medical Assistance Program; and

(b) using the new frame that has been selected and the recipient's lens prescription, the dispensing practitioner shall order a completely new pair of eyeglasses from the optical supplier.

410.486: Vision Care Service Limitations: Lenses

(A) Tinted Lenses.

(1) The Division will pay for "pink 1" and "pink 2" colored lenses, up to 25 percent absorption or equal-density tint, if at least one of the following conditions applies:

(a) the recipient has a pathological or other abnormal condition such as aphakia; or

(b) the recipient has habitually worn tinted lenses of this nature, and the prescriber concludes that the recipient should continue to wear them. The Division will not pay for tinted lenses prescribed only because the recipient complains of photophobia.

(2) Any condition that warrants the use of tinted lenses must be fully documented in the recipient's health care record.

(3) In some situations, other tints (available for plastic lenses only) may be medically justified. Any condition that warrants the use of tinted lenses of this nature must be fully documented in the recipient's health care record, and may be ordered from the optical supplier only after the provider has received prior authorization from the Division.

(B) Coated Lenses. The Division will pay for coated lenses only when they are needed to give equal-density tint or, using clear coatings only, to prevent excessive reflective glare. Any condition that warrants the use of coated lenses must be fully documented in the recipient's health care record.

(C) Cataract Lenses. The Division will not pay for glass cataract lenses. All aphakic prescriptions for recipients requiring cataract lenses must specify plastic lenticular aspheric lenses only. Any condition that warrants the use of cataract lenses must be fully documented in the recipient's health care record.

(D) Contact Lenses.

(1) The Division will pay for hard, soft, or gas-permeable contact lenses if one or more of the following conditions exists:

(a) postoperative cataract extraction;
(b) kerataconus;
(c) anisomatropia of more than 3.00D; or
(d) more than 7.00D of myopia.

(2) Any condition that warrants the use of hard, soft, or gas-permeable contact lenses must be fully documented in the recipient's health care record.

410.487: Vision Care Service Limitations: Other Restrictions

(A) Extra or Spare Eyeglasses. The Division will pay for an extra or spare pair of eyeglasses on a prior authorization basis only. Any condition that warrants the use of an extra or spare pair of eyeglasses must be fully documented in the recipient's health care record. The Division will grant a prior authorization request for extra or spare eyeglasses only if one or more of the following conditions exists:

(1) aphakia;
(2) more than 7.00D of myopia; or
(3) more than 3.00D of astigma.

(B) Two Pairs of Eyeglasses Instead of Bifocals. The Division will pay for two pairs of eyeglasses instead of bifocals if one or more of the following conditions exists. Any condition listed below that warrants the use of two pairs of eyeglasses instead of bifocals must be fully documented in the recipient's health care record.

(1) The recipient's prescription cannot be satisfactorily made into bifocal lenses.
(2) The recipient has shown an inability to adjust to bifocals.
(3) The recipient has a physical disability (for example, severe arthritis) that would preclude or impede adjustment to bifocals.
(4) The recipient's advanced age would make adjustment to bifocals unduly difficult.
(5) The recipient's occupation would make bifocals hazardous.
(6) The recipient has a marked facial asymmetry.

410.488: Vision Care Service Exclusions

(A) The Division will not pay for any of the following services or materials:
(1) absorptive lenses of greater than 25 percent absorption;
(2) photochromatic lenses, sunglasses, or fashion tints;
(3) prisms obtained by decentration;
(4) treatment of congenital dyslexia (the Massachusetts Department of Education may offer resources for the treatment of this condition);
(5) routine adjustments or follow-up visits to check visual acuity and ocular comfort (payment for such visits is included in the dispensing fee for six months after the date on which the eyeglasses were dispensed);
(6) extended-wear contact lenses;
(7) invisible bifocals;
(8) the Welsh 4-Drop Lens; and
(9) substitutions.

(B) If a recipient desires a substitute for or a modification of a reimbursable item, such as photochromatic lenses or designer frames, the recipient must pay for the entire cost of the eyeglasses, including dispensing fees. The Division will not pay for a portion of the cost of the eyeglasses. In all such instances, the provider must inform the recipient of the availability of reimbursable items before dispensing nonreimbursable items.

(C) It is unlawful (M.G.L. c. 6A, s. 35) for a provider to accept any payment from a recipient for a service or item for which payment is available under the Medical Assistance Program. If a recipient claims that he was misinformed about the availability of reimbursable items, it will be the responsibility of the provider to prove that the recipient was offered a reimbursable item, refused it, and chose instead to accept and pay for a nonreimbursable item.

REGULATORY AUTHORITY

130 CMR 410.000: M.G.L. c. 118E, ss. 7 and 12.